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Substitute for form 1449B/PTO			Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			Application Number	
			Filing Date June 20, 2003	
			First Named Inventor Baskaran Chandrasekar	
			Group Art Unit	
			Examiner Name	
Sheet 2	of 9	Attorney Docket Number 201267.90011		

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials ¹	Cite No. ²	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
Amc	—	Akishita, M., et al., "Estrogen Inhibits Cuff-induced Intima Thickening of Rat Femoral Artery: Effects on Migration and Proliferation of Vascular Smooth Muscle Cells," Atherosclerosis 130:1-10, 1997.	
Amc	—	Albuquerque, M.L., et al., "Basic Fibroblast Growth Factor Release by Human Coronary Artery Endothelial Cells is Enhanced by Matrix Proteins, 17-beta Estradiol and a PKC Signaling Pathway," Exp. Cell Res. 245(1):163-169, 1998.	
Amc	—	Asahara, T., et al., "Local Delivery of Vascular Endothelial Growth Factor Accelerates Reendothelialization and Attenuates Intima Hyperplasia in Balloon-injured Rat Carotid Artery," Circulation 91(11):2793-2801, 1995.	
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Amc	—	Bonan, R., et al., "Coronary Restenosis: Evaluation of a Restenosis Injury Index in a Swine Model," Am. Heart J. 126(6):1334-1340, 1993.	
Amc	—	Brewster, M.E., et al., "Use of 2-hydroxypropyl-beta-cyclodextrin as a Solubilizing and Stabilizing Excipient for Protein Drugs," Pharm. Res. 8(6):792-795, 1991.	
Amc	—	Chandrasekar, B. and Tanquay, J.F., "Local Delivery of 17-beta Estradiol Decreases Neointima Hyperplasia Following Coronary Angioplasty in Porcine Model," (submitted for publication).	
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Amc	—	Chen, S.J., et al., "Estrogen Reduces Myointimal Proliferation after Balloon Injury of Rat Carotid Artery," Circulation 93(3):577-584, 1996.	
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Examiner Signature <i>Megan Cotton</i>	Date Considered <i>9/8/03</i>
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		First Named Inventor	Baskaran Chandrasekar
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Sheet	3	of	9
		Attorney Docket Number	201267.90011

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Amc	—	Collins, P., et al., Hemoglobin Inhibits Endothelium-dependent Relaxation to Acetylcholine in Human Coronary Arteries In Vivo," Circulation 87(1):80-85, 1993.	
Amc	—	Cooke, J.P. and Tsao, P.S., "Cytoprotective Effects of Nitric Oxide," Circulation 88(5):2451-2454, 1993.	
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Amc	—	Fischell, T.A., et al., "Coronary Artery Vasoconstriction Routinely occurs after Percutaneous Transluminal Coronary Angioplasty: A Quantitative Arteriographic Analysis," Circulation 78(6):1323-1334, 1988.	
Amc	—	Foegh, M.L., et al., "Estradiol Inhibition of Arterial Neointima Hyperplasia after Balloon Injury," J. Vasc. Surg. 19(4):722-726, 1994.	
Amc	—	Frijlink, H.W., et al., "The Pharmacokinetics of Beta-cyclodextrin and 2-hydroxypropyl-beta-cyclodextrin in the Rat," Pharm. Res. 7(12):1248-1252, 1990.	
Amc	—	Furchgott, R.F. and Zawadzki, J.V., "The Obligatory Role of Endothelial Cells in the Relaxation of Arterial Smooth Muscle by Acetylcholine," Nature 288:373-376, 1980.	

Examiner Signature <i>Alvin L. Latta</i>	Date Considered <i>9/8/2008</i>
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		Attorney Docket Number	201267.90011

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AME	✓	Geary, R.L., et al., "Conjugated Equine Estrogens Inhibit Progression of Atherosclerosis but have no Effect on Intimal Hyperplasia or Arterial Remodeling Induced by Balloon Catheter Injury in Monkeys," J. Am. Coll. Cardiol. 31(5):1158-1164, 1998.	
AME	✓	Gilligan, D.M., et al., "Effects of Physiological Levels of Estrogen on Coronary Vasomotor Function in Postmenopausal Women," Circulation 89(6):2545-2551, 1994.	
AME	✓	Hayashi, Y., et al., "Functional and Anatomical Recovery of Endothelium after Denudation of Coronary Artery," Am. Physiol. Soc. H1081-H1090, 1988.	
AME	✓	Hayashi, T., et al., "Estrogen Increases Endothelial Nitric Oxide by a Receptor-mediated System," Biochem. Biophys. Res. Commun. 214(3):847-855, 1995.	
AME	✓	Hishikawa, K., et al., "Up-regulation of Nitric Oxide Synthase by Estradiol in Human Aortic Endothelial Cells," FEBS Let. 360:291-293, 1995.	
AME	✓	Hoon, T.J., et al., "Bioequivalence of a 17-beta Estradiol Hydroxypropyl-beta-cyclodextrin Complex in Postmenopausal Women," J. Clin. Pharmacol. 33:1116-1121, 1993.	
AME	✓	Hyder, S.M., et al., "Uterine Expression of Vascular Endothelial Growth Factor is Increased by Estradiol and Tamoxifen," Cancer Res. 56(17):3954-3960, 1996.	
AME	✓	Iafrati, M.D., et al., "Estrogen Inhibits the Vascular Injury Response in Estrogen Receptor alpha-deficient Mice," Nat. Med. 3(5):545-548, 1997.	
AME	✓	Karas, R.H., et al., "Human Vascular Smooth Muscle Cells Contain Functional Estrogen Receptor," Circulation 89(5):1943-1950, 1994.	
AME	✓	Karas, S.P., et al., "Coronary Intimal Proliferation after Balloon Injury and Stenting in Swine: An Animal Model of Restenosis," J. Am. Coll. Cardiol. 20(2):467-474, 1992.	
AME	✓	Kauffman, R.F., et al., "Comparative Effects of Local vs. Systemic Administration of Estrogen upon Vascular Responses to Balloon Injury," Circulation 92(8):1628, 1995.	

Examiner Signature <i>Alegand T. Hoon</i>	Date Considered <i>9/8/2003</i>
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		Filing Date	June 20, 2003
		First Named Inventor	Baskaran Chandrasekar
		Group Art Unit	
		Examiner Name	
Sheet 5 of 9	Attorney Docket Number	201267.90011	

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
Amc	✓	Kawana, H., et al., "Gender Differences in Improvement of Endothelium-dependent Vasodilation after Estrogen Supplementation," J. Am. Coll. Cardio. 30(4):914-919, 1997.	
Amc	✓	Keany, J.F., et al., "17-Beta-estradiol Preserves Endothelial Vasodilator Function and Limits Low-density Lipoprotein Oxidation in Hypercholesterolemic Swine," Circulation 89(5):2251-2259, 1994.	
Amc	✓	Kim-Schulze, S., et al., "Expression of An Estrogen Receptor by Human Coronary Artery and Umbilical Vein Endothelial Cells," Circulation 94(6):1402-1407, 1996.	
Amc	✓	Kim-Schulze, S., et al., "Estrogen Stimulates Delayed Mitogen-Activated Protein Kinase Activity in Human Endothelial Cells via an Autocrine Loop that Involves Basic Fibroblast Growth Factor," Circulation 98:413-421, 1998.	
Amc	✓	King, S.B., III, et al., "Endovascular Beta-radiation to Reduce Restenosis after Coronary Balloon Angioplasty: Results of the Beta Energy Restenosis Trial (BERT)," Circulation 97:2025-2030, 1998.	
Amc	✓	Kolodgie, F.D., et al., "Estradiol Attenuates Directed Migration of Vascular Smooth Muscle Cells In Vitro," Am. J. Pathol. 148(3):969-976, 1996.	
Amc	✓	Kraskinski, K., et al., "Estradiol Accelerates Functional Endothelial Recovery after Arterial Injury," Circulation 95(7):1768-1772, 1997.	
Amc	✓	Kristensson, J.K., et al., "Dexamethasone-cyclodextrin-polymer Co-complexes in Aqueous Eye Drops: Aqueous Humor Pharmacokinetics in Humans," Invest. Ophthalmol. Vis. Sci. 37(6):1199-1203, 1996.	
Amc	✓	Kublick, H., et al., "Nasal Absorption of 17-beta-estradiol from Different Cyclodextrin Inclusion Formulations in Sheep," Eur. J. Pharma. Biopharm. 42(6):320-324, 1996.	
Amc	✓	Kuiper, G.G.J.M., et al., "Cloning of a Novel Estrogen Receptor Expressed in Rat Prostate and Ovary," Proc. Natl. Acad. Sci. USA 93:5925-5930, 1996.	
Amc	✓	Kullo, I.J., et al., "Enhanced Endothelium-dependent Relaxations after Gene Transfer of Recombinant Endothelial Nitric Oxide Synthase to Rabbit Carotid Arteries," Hypertension 30(3):314-320, 1997.	

Examiner Signature	<i>[Signature]</i>	Date Considered	7/8/2003
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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
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Amc	✓	Levine, R.L., et al., "Medroxyprogesterone Attenuates Estrogen-mediated Inhibition of Neointima Formation after Balloon Injury of the Rat Carotid Artery," Circulation 94(9):2221-2227, 1996.	
Amc	✓	Lindner, V., et al., "Regrowth of Arterial Endothelium: Denudation with Minimal Trauma Leads to Complete Endothelial Cell Growth," Lab. Invest. 61(5):556-563, 1989.	
Amc	✓	Lindner, V., et al., "Basic Fibroblast Growth Factor Stimulates Endothelial Regrowth and Proliferation in Denuded Arteries," J. Clin. Invest. 85:2004-2008, 1990.	
Amc	✓	Lindner, V., et al., "Increased Expression of Estrogen Receptor- α mRNA in Male Blood Vessels after Vascular Injury," Cir. Res. 83:224-229, 1998.	
Amc	✓	Losordo, D.W., et al., "Variable Expression of the Estrogen Receptor in Normal and Atherosclerotic Coronary Arteries of Premenopausal Women," Circulation 89(4):1501-1510, 1994.	
Amc	✓	Ludmer, P.L., et al., "Paradoxical Vasoconstriction Induced by Acetylcholine in Atherosclerotic Coronary Arteries," N. Eng. J. Med. 315(17):1046-1051, 1986.	
Amc	✓	MacRitchie, A.N., et al., "Estrogen Upregulates Endothelial Nitric Oxide Synthase Gene Expression in Fetal Pulmonary Artery Endothelium," Cir. Res. 81(3):355-362, 1997.	
Amc	✓	Malekianpour, M., et al., "Abnormal Coronary Vasomotion and Angina after Successful Coronary Angioplasty," Circulation 94(8):1-560, 1996 (Abstract).	
Amc	✓	Mancini, G.B.J., et al., "Automated Quantitative Coronary Arteriography: Morphologic and Functional Validation In Vivo of a Rapid Digital Angiographic Method," Circulation 75(2):452-460, 1987.	
Amc	✓	McLaren, J., et al., "Vascular Endothelial Growth Factor is Produced by Peritoneal Fluid Macrophages in Endometriosis and is Regulated by Ovarian Steroids," J. Clin. Invest. 98(2):482-489, 1996.	
Amc	✓	Mendolsohn, M.E. and Karas, R.H., "Estrogen and the Blood Vessel Wall," Curr. Opin. Cardiol. 9:619-626, 1994.	

Examiner Signature	<i>Wigand Colton</i>	Date Considered	9/8/2008
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Amc	—	O'Keefe, J.H., et al., "Estrogen Replacement Therapy after Coronary Angioplasty in Women," J. Am. Coll. Cardiol. 29(1):1-5, 1997.	
Amc	—	Oparil, S., et al., "Sexually Dimorphic Response of the Balloon-injured Rat Carotid Artery to Hormone Treatment," Circulation 95(5):1301-1307, 1997.	
Amc	—	Perrot-Applanat, M., "Questradiol and Proliferation of Vascular Cells," 54(3):333-337, 1999.	
Amc	—	Post, M.J., et al., "The Relative Importance of Arterial Remodeling Compared with Intimal Hyperplasia in Lumen Renarrowing after Balloon Angioplasty," Circulation 89(6):2816-2821, 1994.	

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Amc	✓	Reis, S.E., et al., "Ethinyl Estradiol Acutely Attenuates Abnormal Coronary Vasomotor Responses to Acetylcholine in Postmenopausal Women," <i>Circulation</i> 89(1):52-60, 1994.	✓
Amc	✓	Roselli, M., et al., "Circulating Nitric Oxide (Nitrite/Nitrate) Levels in Postmenopausal Women Substituted with 17-beta-estradiol and Norethisterone Acetate: A Two-year Follow-up Study," <i>Hypertension</i> 25(2):848-853, 1995.	✓
Amc	✓	Sarkar, R., et al., "Nitric Oxide Reversibly Inhibits the Migration of Cultured Vascular Smooth Muscle Cells," <i>Cir. Res.</i> 78(2):225-230, 1996.	✓
Amc	✓	Selzman, C.H., et al., "Estrogen Replacement Inhibits Intimal Hyperplasia and the Accumulation and Effects of Transforming Growth Factor Beta1," <i>J. Surg. Res.</i> 80(2):380-385, 1998.	✓
Amc	✓	Seo, K.K., et al., "Involvement of Endothelial Nitric Oxide Synthase in the Impaired Endothelium-dependent Relaxation of Cavernous Smooth Muscle in Hypercholesterolemic Rabbit," <i>J. Androl.</i> 20(2):298-306, 1999.	✓
Amc	✓	Shimokawa, H., et al., "Porcine Coronary Arteries with Regenerated Endothelium have a Reduced Endothelium-dependent Responsiveness to Aggregating Platelets and Serotonin," <i>Cir. Res.</i> 61(2):256-270, 1987.	✓
Amc	✓	Speir, E., et al., "Estrogen Inhibits Transcription Factor and Cell Adhesion Molecule Activation in Cytokine-stimulated Human Coronary Smooth Muscle Cell via Antioxidant Effects," <i>Circulation Suppl.</i> 1:1-220, 1998 (Abstract).	✓
Amc	✓	Spyridopoulos, I., et al., "Estrogen-receptor-mediated Inhibition of Human Endothelial Cell Apoptosis: Estradiol as a Survival Factor," <i>Circulation</i> 95(6):1505-1514, 1997.	✓
Amc	✓	Sullivan, T.R., Jr., et al., "Estrogen Inhibits the Response-to-injury in a Mouse Carotid Artery Model," <i>J. Clin. Invest.</i> 96:2482-2488, 1995.	✓
Amc	✓	Tanaka, H., et al., "Sustained Activation of Vascular Cells and Leukocytes in the Rabbit Aorta after Balloon Injury," <i>Circulation</i> 88(4):1788-1803, 1993	✓
Amc	✓	Tanaka, H., et al., "Proliferating Arterial Smooth Muscle Cells after Balloon Injury Express TNF-alpha but not Interleukin-1 or Basic Fibroblast Growth Factor," <i>Arterioscler. Thromb. Vasc. Biol.</i> 16(1):12-18, 1996.	✓

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Sheet 9 of 9		Application Number	
		Filing Date	June 20, 2003
		First Named Inventor	Baskaran Chandrasekar
		Group Art Unit	
		Examiner Name	
		Attorney Docket Number	201267.90011

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Amc	—	Teirstein, P.S., "Catheter-based Radiotherapy to Inhibit Restenosis after Coronary Stenting," N. Engl. J. Med. 336(24):1697-1703, 1997.	
Amc	—	Varenne, O., et al., "Local Adenovirus-mediated Transfer to Human Endothelial Nitric Oxide Synthase Reduces Liminal Narrowing After Coronary Angioplasty in Pigs," Circulation 98:916-926, 1998.	
Amc	—	Venkov, C.D., et al., "Identification of Authentic Estrogen Receptor in Cultured Endothelial Cells: A Potential Mechanism for Steroid Hormone Regulation of Endothelial Function," Circulation 94(4):727-733, 1996.	
Amc	—	Weiner, C.P., et al., "Induction of Calcium-dependent Nitric Oxide Synthases by Sex Hormones," Proc. Natl. Acad. Sci. USA 91:5212-5216, 1994.	
Amc	—	Wellman, G.C., et al., "Gender Differences in Coronary Artery Diameter Involve Estrogen, Nitric Oxide, and Ca ²⁺ -dependent K ⁺ Channels," Circ. Res. 79(5):1024-1030, 1996.	
Amc	—	Williams, J.K., et al., "Short-term Administration of Estrogen and Vascular Responses of Atherosclerotic Coronary Arteries," J. Am. Coll. Cardio. 20(2):452-457, 1992.	
Amc	—	Yoon Young-Sup, et al., "Local Intraluminal Infusion of Oestradiol Containing Liposome in Rat Carotid Balloon Injury Model," Eur. Heart J. 19:616, 1998.	
Amc	—	Zhang, Y.-Q., et al., "Effects of Gender and Estradiol Treatment on Focal Brain Ischemia," Brain Res. 784(1/2):321-324, 1998.	

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